UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

Barbe Puro, on behalf of herself and all others similarly situated,

Plaintiff,

v.

New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center,

Defendant.

Court File No.

Class Action

Complaint

Plaintiff Barbe Puro, on behalf of herself and all others similarly situated, by and through her undersigned counsel, brings this Complaint in class action and alleges as follows:

Summary of Class Action

1. Plaintiff Barbe Puro ("Plaintiff"), a resident of the state of Minnesota, received epidural injections of a steroid to ease her chronic back pain.

2. The steroid, methylprednisolone acetate, was manufactured by defendant New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC").

3. Unknown to Plaintiff, or medical staff administering the injections, a fungus contaminated the steroid, rendering the material dangerous and unfit for use. NECC produced and sold more than 17,000 single-dose vials of the steroid, which are believed to be contaminated.

4. This case seeks redress for NECC's sale of the defective and dangerously contaminated steroid, which has caused Plaintiff and others bodily harm, emotional distress, other personal injuries, and to incur medical and other expenses.

5. NECC voluntarily recalled the steroid, along with scores of other medicines, after the Center for Disease Control and Prevention ("CDC") confirmed an outbreak of fungal meningitis in people who received injections of the steroid.

6. According to the CDC, "[f]ungal meningitis occurs when the protective membranes that cover the brain and spinal cord are infected with a fungus. Fungal meningitis can develop after a fungus spreads through the bloodstream from somewhere else in the body, as a result of the fungus being introduced directly into the central nervous system, or by direct extension from an infected body site next to the central nervous system."

7. As of the filing of this complaint, the CDC was aware of and had confirmed 170 instances in which a person developed fungal meningitis after receiving a steroid injection produced by NECC. This outbreak is present in ten states, including Minnesota. At least fourteen people have died as a result of developing fungal meningitis through an injection of the steroid sold by NECC, according to the CDC.

Plaintiff

8. Plaintiff Barbe Puro is a resident of Savage, Minnesota. At all relevant times, Plaintiff has been a resident and citizen of Minnesota.

9. Plaintiff brings this action on behalf of herself and on behalf of residents of Minnesota who suffered bodily harm, emotional distress, and other personal injuries after being injected with doses of NECC's contaminated steroid.

Defendant

10. NECC is in the business of manufacturing, marketing, and selling medicines. Among the products that NECC manufactures, markets, and sells is methylprednisolone acetate, an injectable steroid.

11. NECC is a Massachusetts corporation that maintains its principal place of business at 697 Waverly Street in Framingham, Massachusetts.

Jurisdiction and Venue

12. This Court has jurisdiction over the parties, the putative class, and the causes of action asserted herein pursuant to Rule 23 of the Federal Rules of Civil Procedure and under the Class Action Fairness Act, 28 U.S.C. § 1332(d), as the amount in controversy exceeds $5 million.

13. Venue in this forum is proper because Plaintiff resides in Minnesota, the putative class members reside in Minnesota, the causes of action for Plaintiff arose, in part in Minnesota, and the causes of action for putative class members arose, in part, in Minnesota.

14. NECC conducts business within Minnesota, delivers product to Minnesota, and purposefully directs sales and marketing efforts to Minnesota and its residents.

Factual Background

NECC's production of contaminated steroid

15. NECC is a compounding pharmacy, which means NECC creates custom-mix solutions, creams, and other medications in doses or forms that generally are not commercially available.

16. Compounding pharmacies, such as NECC, are not closely regulated like drug manufacturers, and the products they create are not subject to approval by the Food and Drug Administration ("FDA").

17. NECC manufactured the injectable steroid methylprednisolone acetate at its Massachusetts facility, and it sold tens of thousands of single-dose vials of the substance.

18. In early October 2012, FDA investigators located fungal contamination in a sealed vial of the steroid at NECC's facilities. The discovery prompted NECC to recall 17,676 single-dose vials of the steroid.

Widespread impact

19. But, even though NECC recalled the steroid in early October, thousands of people at outpatient clinics and similar facilities in 23 states, including Minnesota, were injected with the steroid between July and September 2012.

20. The CDC has confirmed 170 cases in which people developed fungal meningitis after receiving the contaminated steroid. At least fourteen people have died as a result of receiving the contaminated injectable steroid. The incubation period for fungal meningitis is anywhere between a few days to one month, so health officials believe the number of victims will increase.

21. According to the CDC, people who develop fungal meningitis may have symptoms that include: headache, fever, nausea, and stiffness of the neck. Infected people may also feel confused, dizzy, or discomfort from bright lights.

22. Some of the people who received the contaminated steroid have suffered strokes as a result of the tainted injection.

Minnesota impact

23. According to the CDC, at least six clinics and facilities in Minnesota received and potentially administrated the contaminated steroid: MAPS-Edina Medical Pain Clinic; MAPS-Medical Advanced Pain; two locations of Medical Advanced Pain Specialists; and two locations of Minnesota Surgery Center. The six clinics and facilities are located in or near Minneapolis and St. Paul.

24. The Minnesota Department of Health ("MDH") estimates that nearly 1,000 people might have been injected with the contaminated steroid at clinics and facilities in Minnesota.

Plaintiffs' story of being injected with NECC's contaminated steroid

25. Plaintiff received injections of NECC's contaminated steroid on September 17, 2012, at the MAPS location in Shakopee, Minnesota.

26. After receiving the injections, Plaintiff suffered headaches and nausea for approximately a week.

27. Plaintiff then received a call from the MDH informing her that she had received the contaminated steroid sold by NECC and directing her to see a physician to be evaluated for potential fungal meningitis.

28. Plaintiff underwent medical testing including medical blood work and laboratories, a spinal tap, and other analyses as a result of being injected with NECC's defective and contaminated steroid.

29. Plaintiff has suffered personal injuries, emotional distress, and has incurred medical and other expenses as a direct result of being exposed to NECC's defective and contaminated steroid.

Proposed Class Definitions

30. Plaintiff brings this class action on behalf of herself and all others similarly situated, for all claims alleged herein, pursuant to Rule 23 of the Federal Rules of Civil Procedure. The proposed class is defined as:

> All persons who reside in Minnesota and who received an injection containing contaminated methylprednisolone acetate manufactured by New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center, from June 2012 to the present.

31. Plaintiff specifically excludes NECC and its related entities from the putative class, all subsidiaries or affiliates of NECC; any entity in which NECC has a controlling interest; and any and all of NECC's employees, affiliates, legal representatives, heirs, successors, or assignees.

32. Plaintiff also excludes from the putative class any person or entity that has previously commenced and concluded a lawsuit against NECC arising out of the subject matter of this lawsuit.

33. Plaintiff also specifically excludes from the putative class the judge assigned to this case and any member of the judge's immediate family.

34. Plaintiff and her counsel reserve the right to modify or amend the class definitions, if appropriate, as this case proceeds.

Satisfaction of Class Prerequisites

35. This class action satisfies numerosity, commonality, typicality, adequacy, and superiority requirements for maintaining a class.

36. Certification of Plaintiff's claims for class-wide treatment is appropriate because Plaintiff can prove the elements of her claims, and can disprove NECC's defenses, using common, class-wide evidence.

37. **Numerosity.** Pursuant to Rule 23(a)(1) of the Federal Rules of Civil Procedure, the putative class "is so numerous that joinder of all members is impracticable." The number of members of the putative class is about one thousand people who were injected with the contaminated steroid.

38. Joinder of the persons and entities who received the contaminated steroid injection is impractical and not feasible.

39. **Ascertainability.** Membership in the putative class is easily ascertained through the records of medical facilities, outpatient clinics, and similar facilities at which people received injections of the contaminated steroid.

40. NECC's recall of the contaminated steroid establishes that identifying putative class members will be easily accomplished through its records and the prescribing records of the administering medical professionals.

41. **Commonality.** Pursuant to Rule 23(a)(2) of the Federal Rules of Civil Procedure, the putative class shares "questions of law or fact" that predominate and

individualized issues. The evidence in this case will provide answers to questions that are common to members of the class. Those questions, for which common evidence will provide answers, include, but are not limited to, the following:

- Were NECC's methylprednisolone acetate steroid doses defectively designed for their intended application, and if so, what is the nature of the design defect?
- Were NECC's methylprednisolone acetate steroid doses defectively manufactured for their intended application, and if so, what is the nature of the manufacturing defect?
- Did NECC exercise reasonable care in the design, manufacture, and testing of the methylprednisolone acetate steroid doses?
- Were NECC's methylprednisolone acetate steroid doses unreasonably dangerous for their expected and intended use?
- Did NECC fail to warn about the dangers associated with its methylprednisolone acetate steroid doses?

42. **Typicality.** Pursuant to Rule 23(a)(3) of the Federal Rules of Civil Procedure, the claims of the putative class representative "are typical of the claims ... of the class." Plaintiff and all members of the putative class who were injected with the contaminated steroid have suffered damages as a result of NECC's wrongful acts and misconduct.

43. **Adequacy.** Pursuant to Rule 23(a)(4) of the Federal Rules of Civil Procedure, the putative class representative "will fairly and adequately protect the interests of the class." Plaintiff has no adverse interests to the putative class members. Plaintiff received injections that contained the contaminated steroid manufactured by NECC. Plaintiff has retained lawyers who have substantial resources, experience, and success in the prosecution

and defense of class action, mass tort, and complex litigation, and the insurance coverage and settlement issues attendant to the same.

44. **Superiority.** Pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure, a class action is a superior method of resolving this action for the following reasons:

a. A class action in this instance conserves the resources of the putative class, NECC, and the Court.

b. On information and belief, no Attorney General of any state has brought an enforcement action against NECC to remedy the claims asserted herein.

c. Serial adjudications in numerous venues are not efficient, timely, or proper. Judicial resources throughout the United States will be unnecessarily depleted by resolution of individual claims.

d. Individualized judgments and rulings could result in inconsistent relief for similarly situated plaintiffs. Individualized lawsuits could also establish incompatible standards of conduct for NECC in creating, marketing, sale and post-sale conduct in connection with its products.

Count I

(Strict Liability)

45. Plaintiff and the putative class members re-allege the foregoing paragraphs, inclusive, as though fully set forth herein.

46. Upon information and belief, NECC is the exclusive designer and manufacturer of the contaminated methylprednisolone acetate steroid doses and is solely responsible for its introduction to the market.

47. The contaminated methylprednisolone acetate steroid doses reached Plaintiff and the putative class members without a substantial change in the condition in which they were manufactured and intended for use.

48. NECC had a duty to use reasonable care in designing and manufacturing the methylprednisolone acetate steroid doses such that they are not unreasonably dangerous to users when used as directed or in a way foreseeable to NECC.

49. NECC breached that duty by designing and manufacturing the methylprednisolone acetate steroid doses in a defective condition unreasonably dangerous to the Plaintiff and the putative class.

50. The methylprednisolone acetate was defective because: (1) the substance diverged from its intended design and was tainted with fungal matter that harmed Plaintiff and the putative class; and (2) the design and manufacturing did not satisfy normal consumer expectations.

51. If the methylprednisolone acetate steroid doses had been properly designed and manufactured, Plaintiff and the putative class members would not have been harmed.

52. As a direct and proximate result of NECC's breach of its duty to use reasonable care in the design and manufacture of methylprednisolone acetate, Plaintiff and the putative class members have suffered serious bodily harm, other personal injuries, and emotional distress, and have incurred medical and other expenses.

53. NECC is strictly liable to the Plaintiff and the putative class members for its defective design and manufacture of methylprednisolone acetate in an amount to be proven at trial.

Count II

(Negligence)

54. Plaintiff and the putative class members reallege the foregoing paragraphs, inclusive, as though fully set forth herein.

55. NECC was negligent because it failed to use reasonable care when it designed, tested, manufactured, marketed, and sold doses of methylprednisolone acetate.

56. As the designer, tester, manufacturer, and / or seller of consumer products, NECC owed a duty to Plaintiff and the putative class members to provide a safe and quality product. NECC breached those duties.

57. As a direct and proximate result of NECC's negligence, lack of care, and other wrongful acts, Plaintiff and the putative class members sustained and will sustain damages.

58. As a result of NECC's negligence, Plaintiff and the putative class members have suffered serious bodily harm, other personal injuries, and emotional distress, and have incurred medical and other expenses as a direct cause of being injected with contaminated doses of methylprednisolone acetate.

59. As a direct, proximate and foreseeable result of NECC's negligence, Plaintiff and the putative class members have been damaged in an amount to be determined at trial.

Prayer for Relief

WHEREFORE, Plaintiff, on behalf of herself and all others similarly situated, prays for relief against NECC as follows:

1. Certification of this matter as a class action and appointing Plaintiff and her counsel to represent the class;

2. Compensation for damages suffered by Plaintiff and the putative class members;

3. Award of reasonable attorneys' fees and costs and disbursements incurred herein;

4. Award of additional damages, remedies, and penalties available by law;

5. Declaring the rights and obligations of the parties as prayed for; and

6. Such other and further relief the Court deems just and equitable.

Dated: 10/11/12

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